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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Ear hook assembly for a cochlear implant system

The invention is described in the following statement:

Field of the Invention

The present invention relates to a cochlear implant system. In particular, the present invention relates to an external component of a cochlear implant system that facilitates alignment of the external transmitter coil with an implanted internal receiver coil.

Background of the Invention

In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Typically, cochlear implant systems have consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter coil which is positioned to communicate with an implanted receiver coil provided with the stimulator/receiver unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit traditionally includes a receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

Traditionally, the speech processor has been carried on the body of the user, such as in a pocket of the user's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip behind the ear or on the lapel of the user.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the user. This unit allows the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with a cable extending to the external transmitter coil that is still positioned on the side of the user's head and magnetically aligned with the internal receiver coil to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

The external transmitter coil has traditionally been held in place via a magnet which aligns with a magnet positioned within the internal receiver coil. Such a secure alignment ensures that both coils are coupled efficiently so that the transfer of data and power is effectively performed. Whilst aiding in proper coil alignment, such a connection also provides a firm and secure method of holding the external coil in position on the head of the user, with the strength of this securing force being adjustable through the use of variable strength magnets in the external coil. This method of securing the external and internal coils in close alignment has been found to be quite important for children and the like who are active and mobile and as such require a simple, yet effective means of ensuring that alignment of the coils is maintained. Early devices attempted to facilitate alignment of the internal and external coils through a headband arrangement that was fitted around the head of the user to hold the coil in place. Such an arrangement proved troublesome as it could easily be knocked or unintentionally adjusted, especially with small children, and as such communication could easily be lost or reduced between the external device and the implant. Such an arrangement was also not aesthetically pleasing.

A downside of the present system is the fact that for some people, the external coil is quite visible and cannot be easily hidden and as such they are conscious of this and the fact that their device is noticeable to others. Therefore it is highly desirable to provide a system wherein the external components are relatively comfortable and easily worn so that the user does not feel stigmatised or self-conscious wearing the device.

Another issue with prior art devices is the fact that the magnet used to facilitate and maintain proper alignment of the coils, prevents, or is detrimental to the effective use of magnetic resonance imaging (MRI) techniques, in the head region surrounding the implanted magnet. The presence of the magnet in such instances can distort the image taken from such a technique and in some instances the technique may even cause the implanted magnet to move, causing problems with the implanted device. Therefore it would be highly desirable to provide an implant that allows recipients to utilise such a valuable medical diagnostic tool as an MRI, and ensure that such a technique can be undertaken without the risk of damage to the patient and/or device.

In order to overcome these disadvantages magnetless cochlear implants have been proposed, such as that disclosed in US Patent Number 6,141,591. This patent discloses an implant that is strategically positioned via a set of alignment tools so that it can be aligned to communicate with an external controller/transmitter without the need for a magnet. The method of implantation requires a set of specific steps to ensure that the device is embedded into the skull at the appropriate position, so that in use, the implant coil communicates with an external coil incorporated in an external unit worn behind the ear of the recipient. One problem with this particular device and method is that it requires the implant to be implanted by a relatively highly skilled surgeon to ensure the implant is positioned in the correct place. Still further, should there be a change in the head shape, such as that which occurs during a child's growth, the implant may be placed such that the alignment with the external unit is not possible or ideal.

The present invention provides a cochlear implant system that is adapted to address the above deficiencies of the prior art.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, this application is directed to a first invention comprising an external component of a cochlear implant system, the external component comprising a supporting means for mounting to the ear of an implantee and an external signal transmitting means, wherein the signal transmitting means is movably mounted to at least a portion of the supporting means.

In one embodiment, the external transmitting means comprises a transmitter coil. The transmitter coil is preferably adapted to provide in combination with an implanted receiver coil a transcutaneous radio frequency (RF) link between the external component of the cochlear implant system and implanted componentry thereof.

In a still further embodiment, the supporting means comprises a housing having an ear hook member. The member preferably extends forwardly from the housing and is adapted, when used, to sit over the outer ear of the implantee. On mounting to the outer ear, the housing is preferably positioned behind the outer ear.

In one embodiment, the external transmitter coil can be movably mounted to the housing of the supporting means. In this embodiment, the transmitter coil can be mounted to a bracket that is slidably mounted to the housing. In one embodiment, the transmitter coil can be slidably adjustable up and down the housing. In one embodiment, the transmitter coil can be slidably adjustable along or parallel to a longitudinal axis thereof. In addition to or instead of the longitudinal movement, the transmitter coil can be movably adjustable across the housing. In this embodiment, the transmitter coil can slidably move across the housing along or parallel to a lateral axis of the housing.

In a still further embodiment, the housing of the external component can be relatively movably mounted to the ear hook member. In this embodiment, the external component can be relatively slidably movable with respect to the ear hook member. In this case, the transmitter coil can be fixed or relatively movably mounted to the housing or the ear hook member.

In addition to being slidably movable in one direction, the housing can be relatively adjustable in other orientations to the ear hook member.

In yet another embodiment, the transmitter coil can be mounted to an arm extending outwardly from the housing. In a preferred embodiment, the arm can have a first non-movable portion extending rearwardly therefrom and a second movable portion adapted to articulate through a joint with the first portion. In one embodiment, the second portion preferably extends generally upwardly from the joint with the first portion. The external transmitter coil is preferably supported at a distal end of the second portion of the arm. The second portion can include a telescopic portion that can telescopically extend or retract to provide further finer adjustment of the position of the transmitter coil.

In a preferred embodiment, the joint is a universal joint so allowing freedom of movement of the second portion relative to the first portion. The joint is preferably adapted to only move on application of hand pressure to the movable portion of the arm. As such, the second portion is preferably hand adjustable by the implantee or a third person but is resistant to inadvertent movement caused by movement of the head or relatively soft knocks.

In each of the above embodiments, the supporting means can further comprise a locking means adapted to lock the bracket, or the housing, or the second portion of the arm in a desired position. In one embodiment, the locking means can comprise a grub screw that passes through the relatively movable portion of the supporting means and can be hand turned to frictionally engage another portion of the supporting means thereby preventing further movement.

In a preferred embodiment, the cochlear implant system comprises an implanted component comprising a receiver coil and a housing for a stimulator means. A first electrode assembly adapted to be inserted in the cochlea of the implantee preferably extends outwardly from the housing of the stimulator means.

In a further embodiment, the first electrode assembly comprises a carrier member having a leading end that is insertable into a cochlea of an implantee and a trailing end distal the leading end. The elongate carrier member preferably has a plurality of electrodes mounted thereon. In one embodiment, the electrodes are mounted in a longitudinal array. Each of the electrodes have at least one wire, and preferably at least two, extending from each electrode back towards the trailing end of the carrier member.

The wires preferably extend back to the housing to at least a first feedthrough in the wall of the housing. In one embodiment, the feedthrough is positioned in a lower face of the housing. In one embodiment, the feedthrough provides hermetic and insulated electrical connection for each wire extending from the electrode assembly into the housing of the implantable component. Each feedthrough can be formed using the method described in US Patent 5046242, the contents of which are incorporated herein by reference.

In one embodiment, the carrier member can have 22 electrodes. In another embodiment, the carrier member can have 30 or more electrodes. The electrodes are preferably formed from a biocompatible electrically conducting material, such as platinum.

The elongate carrier member is preferably formed from a resiliently flexible material. In one embodiment, the carrier member can be preformed from a plastics material with memory.

In a preferred embodiment, the orientation of the carrier member as it is firstly inserted through a cochleostomy into the cochlea is preferably substantially straight. More preferably, the implantable orientation is straight. Following completion of implantation, the carrier member preferably adopts a spirally curved configuration that matches the spiral nature of the scala tympani of the human cochlea. The carrier member is preferably pre-formed with this spiral configuration and is then straightened either during manufacture and packaging of the device or prior to implantation.

In a preferred embodiment, the elongate carrier member is formed from a suitable biocompatible material. In one embodiment, the biocompatible material can be a silicone, such as a flexible silicone elastomer-Silastic. Silastic MDX 4-4210 is an example of one suitable silicone for use in the formation of the elongate member. In another embodiment, the elongate carrier member can be formed from a polyurethane or similar material.

In a preferred embodiment, a second electrode assembly also extends outwardly from the housing of the stimulator means. While it can be envisaged that the second electrode assembly could also be insertable in the cochlea, it is preferred that the second electrode assembly has one or more electrodes thereon and is adapted to be implantable external of the internal passages, such as the scala tympani, of the cochlea.

The second electrode assembly preferably extends from the housing, once implanted, at least initially in an upward orientation with respect to the implantee's head. In a further embodiment, the second electrode assembly preferably extends from an upper side of the housing. This second electrode assembly is typically implanted external of the cochlea in the muscle surrounding the head of the user. In this instance, the electrode assembly is referred to as an extra-cochlear electrode assembly and this allows the stimulation method known as monopolar stimulation to be performed. In monopolar stimulation, the stimulation passes between an intracochlear and an extracochlear electrode, allowing for a wide current spread not normally achieved through inter-action between intracochlear electrodes only.

The second electrode assembly preferably has one or more features defined herein in relation to the first preferably intracochlear electrode assembly. In a preferred embodiment, the second electrode assembly has one or two electrodes thereon.

In a further embodiment, the housing is preferably implantable in a recess of the temporal bone adjacent the ear of the implantee that is receiving the output of the implant system. The housing is preferably formed from a biocompatible material or has a biocompatible coating. The housing can be coated with a layer of silicone or parylene.

As already discussed, the implantable component preferably also comprises a receiver coil. The receiver coil preferably comprises a wire antenna coil. The antenna coil can be comprised of at least one, and preferably at least three, turns of electrically insulated platinum or gold wire tuned to parallel resonance by a capacitor internal to the housing. The electrical insulation of the antenna coil can be provided by a flexible silicone moulding and/or silicone or polyurethane tubing. The external coil can be constructed in a similar fashion to the implanted coil or have a different construction.

The antenna coil is preferably external of the housing and is very thin enabling the coil, if desired, to be implanted behind the ear. Electrical connection between the antenna coil and componentry of the implantable componentry within the housing can be provided by two hermetic and electrically insulated ceramic feedthroughs or an electrical conductor. The ceramic feedthroughs can be formed using the method described in abovementioned US Patent 5046242.

The receiver coil preferably has a maximum thickness that is less than the maximum thickness of the housing. In one embodiment, the antenna coil preferably has a thickness of about 2.5mm whereas the housing preferably has a maximum thickness of about 3.5mm. The antenna coil preferably has a diameter of about 25mm.

The antenna coil of the implantable component preferably acts as part of the radio frequency (RF) link to allow transcutaneous bidirectional data transfer between the implantable component and external components of the system. The radio frequency signals can be modified to encode data using the method described in US Patent 5741314. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals for the purpose of telemetry from the implanted receiver/stimulator unit.

The link between the two coils also provides a means of powering the componentry of the internal component. In the case where the implantable component further has an on-board or implantable power source, such as a rechargeable battery, the link can provide a means of inductively charging the battery when required.

The implanted housing preferably contains, in addition to the stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from the external component.

The housing of the external component preferably houses a speech processor adapted to receive signals output by a microphone. In a preferred embodiment, the microphone can be mounted to the housing or the ear hook member Other suitable locations for the microphone and/or the housing for the speech processor can be envisaged, such as a lapel of the implantee's clothing.

The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means demodulates the modulated FM signal and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external component preferably further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the microphone, speech processor and power supply can also be implantable. In this embodiment, these components can be contained within a hermetically sealed housing or the housing used for the stimulator means.

As the external coil is preferably positioned on the supporting means having an ear hook member, it will be understood that the external coil will typically be positioned immediately behind or close to the outer ear. The implanted coil is preferably positioned on implantation to be alignable with an external coil in this position. The movable mounting of the external transmitter to at least a portion of the supporting means preferably allows the implantee or a third person to adjust the position of the external coil to achieve optimum alignment of the external coil to the implanted coil.

This property of being adjustable provides a cochlear implant system that can adjust to growth in dimensions of the implantee's head as can be expected as a baby grows into childhood and then further into adulthood.

Still further, this property allows an implantee to use a more discreet magnetless system with the majority of the external component positioned behind the outer ear of the implantee and without the need for a separate coil and associated leads which is currently the case. As such, the external component is far less noticeable to other persons. Indeed, for a person with long and/or thick hair that extends over the ears, the presence of the external component may not be noticeable to casual inspection.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a one example of a prior art cochlear implant system;

Fig. 2 is a side view of one embodiment of an external component of a cochlear implant system according to the present invention;

Fig. 3 is a side view of another embodiment of a external component; and

Fig. 4 is a side view of another embodiment of an external component.

Preferred Mode of Carrying out the Invention

A simplified conventional cochlear implant is shown in Figure 1. Cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes an on-board microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4,532,930.

The sound processor 29 of the cochlear implant can perform an audio spectral analysis of the acoustic signals and outputs channel amplitude levels. The sound processor 29 can also sort the outputs in order of magnitude, or flag the spectral maxima as used in the SPEAK strategy developed by Cochlear Ltd.

One example of a supporting device according to the present invention is depicted generally as 50 in Fig. 2. The supporting device is a modified version of the housing for the speech processor 29 depicted in Fig. 1. The supporting device 50 has an ear hook 51 which is capable of securing the device in place behind the ear of the user, as well as a body 52 which can house a power source and/or a speech processor. A microphone can be placed on the ear hook 51 as described with reference to Figure 1.

In Fig. 2, the external transmitter coil 53 is integrally formed with the body 52 of the device 50 so that when in place the coil 53 provides a radio frequency link with the internal coil of the implant. While integrally formed with the body 52, the body 52 is, in the embodiment depicted in Fig. 2, movably adjustable relative to the ear hook 51. As such, the position of the coil 53 can be adjusted to be brought into alignment with the position of the internal coil by adjusting the position of the body 52 relative to the ear hook.

In the depicted embodiment, the body 52 is mounted to the ear hook 51 through a universal joint 54 that allows the body 52 to move relative to the ear hook 51.

Fig. 3 depicts another embodiment of a supporting device according to the present invention generally as 60. In this embodiment, the device 60 utilises an ear hook element 62 to maintain the device in place behind the outer ear of the implantee. Again, the body 61 of the device is adjustable relative to the ear hook element 62 by having the body 61 mounted on a slider 63 which can be moved relative to the ear hook element 62 in the directions depicted by arrow A. The body 61 can house a speech processor and/or power source as previously described.

The relative adjustment of the body 61 to the ear hook element 62 allows the position of the coil 53 to be adjusted to take into consideration variations in the position of the internal coil, to ensure that optimum alignment is provided.

Yet another embodiment of a possible supporting device is depicted generally as 70 in Fig. 4. In this embodiment, the device 70 again has an ear hook element 71 and a body 72. The hook element 71 can support a microphone and the body 72 house a speech processor and/or power source as previously described. Extending rearwardly from the body 72 is an arm 73 having a first portion 74 that is rigidly mounted to the body 72 and a second portion 75. The second portion 75 is slidably mounted in a tubular orifice in the first portion 74 thereby allowing the orientation of the second portion 75 relative to the first portion 74 to be adjustable by the implantee or a third person.

A distal end of the second portion 75 supports the centre of the external coil 53. As depicted, the second portion 75 includes a telescopic portion 76 that can telescopically extend or retract to allow further finer adjustment of the coil 53.

The present invention provides a means of readily adjusting the orientation and position of the external coil of a cochlear implant system so as to ensure the external coil is in correct alignment with the implanted coil of the system. The system also does not require use of a magnet to ensure maintenance of alignment with attendant advantages of reduced implant size, avoidance of the need to surgically remove the magnet to undergo magnetic resonance imaging, and improved aesthetics for the external component.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this eighth day of March 2002

Cochlear Limited
Patent Attorneys for the Applicant:

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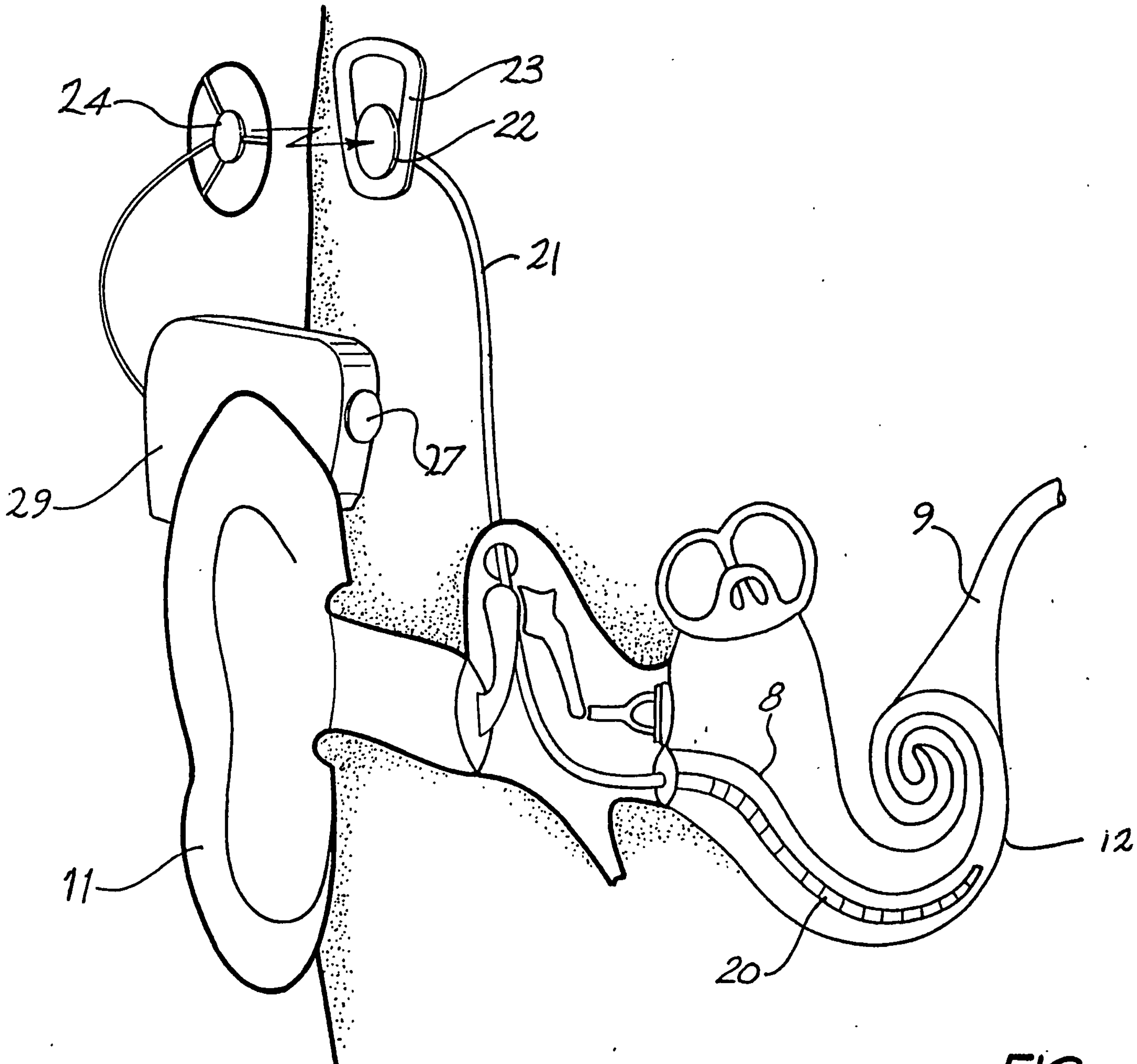

FIG. 1

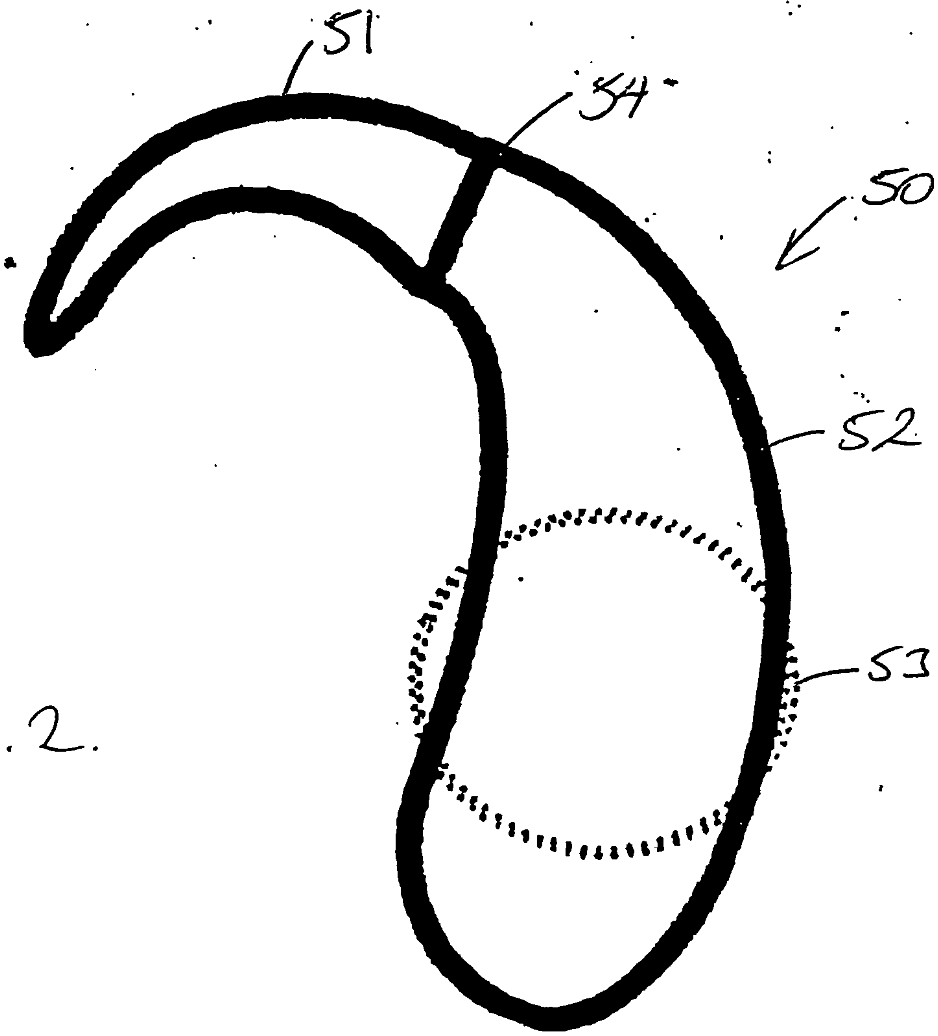

Fig. 2.

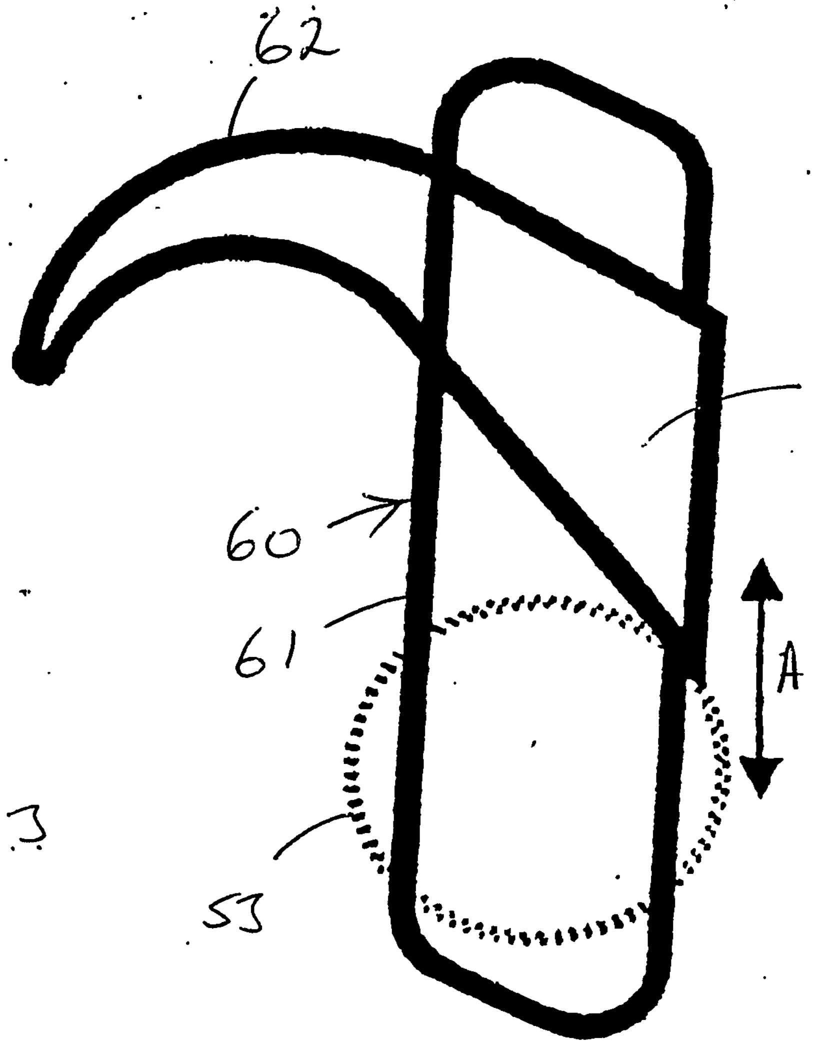

Fig. 3

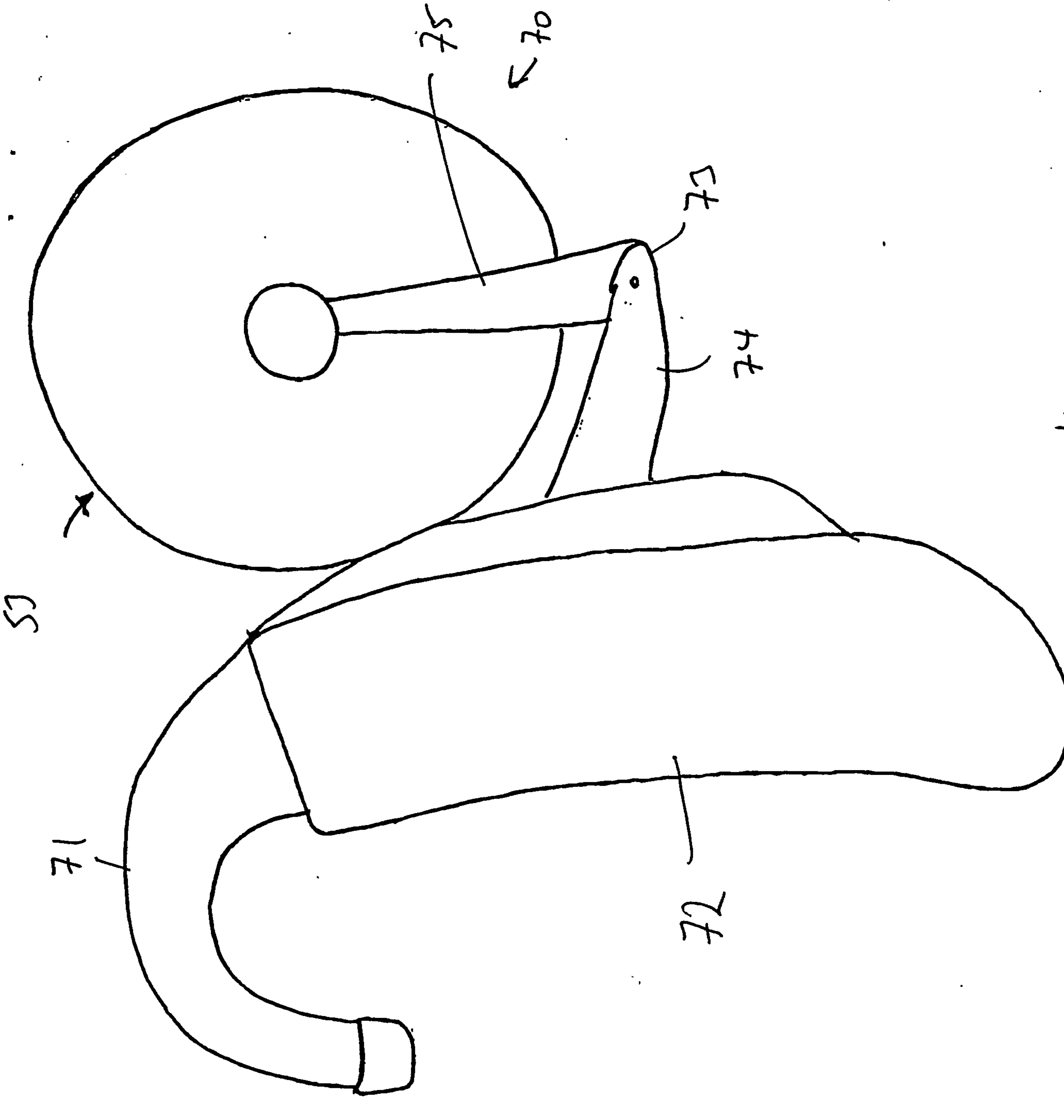

Figure 4